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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,112	09/27/2006	Murray Goodman	00015-038US1/SD2001-203-1	6290

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EXAMINER	
JONES, DAMERON LEVEST	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
12/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,112	GOODMAN ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-7 and 11-14* is/are allowed.

6)☒ Claim(s) *8-10 and 15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Bibliographic Data Sheet & Filing Receipt Confirmation.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 9/27/10 wherein the specification was amended; claims 1-3, 5, and 8 were amended.

Note: Claims 1-19 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments and/or amendment filed /27/10 to the rejection of claims 2, 3, and 5 made by the Examiner under 35 USC 112 (first and second paragraphs) have been fully considered and deemed persuasive because Applicant amended the claims to overcome the rejections. Therefore, the said rejections are hereby withdrawn.

NEW GROUNDS OF REJECTIONS

112 First Paragraph Rejection (Enablement)

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 8-10, 15, 16, and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue

experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to methods of visualizing malignant cells, cell proliferative disorders, and treating prolactin secreting adenomas, restenosis, diabetes mellitus, hyperlipidemia, insulin insensitivity, Syndrome X, angiopathy, proliferative retinopathy, dawn phenomenon, nephropathy, gastric acid secretion, peptic ulcers, enterocutaneous and pancreticocutaneous fistula, irritable bowel syndrome, Dumping syndrome, watery diarrhea syndrome, AIDS related diarrhea, chemotherapy induce diarrhea, acute or chronic pancreatitis, gastrointestinal hormone secreting tumors, *cancer*, hepatoma, angiogenesis, inflammatory disorders, arthritis, chronic allograft rejection, and angioplasty, graft vessel bleeding or gastrointestinal bleeding.

(2) State of the prior art

The state of the prior art is that cancer therapy, for example, remains highly unpredictable. The various types of cancers have different causative agents, involve different cellular mechanisms, and consequently, differ in treatment protocol. It is known (see Golub et al., Science, October 15, 1999, pp. 531-537) that the challenge of

cancer treatment has been to target specific therapies to pathogenetically distinct tumor types in order to maximize efficacy and minimize toxicity. The classification of cancer has been based primarily on morphological appearance of the tumor and that of tumors with similar histopathological appearance may follow significantly different clinical courses and have different responses to therapy (see Golub et al., Science, October 15, 1999, pp. 531-537). As a result, there is no absolute predictability of which tumors are treatable, even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the knowledge in the art would hinder one of ordinary skill in the art from accepting any therapeutic regimen as being acceptable for all tumor/cancer treatments.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. There is no evidence of record which would enable the skilled artisan in the identification of the subjects who have the potential of becoming afflicted with the numerous diseases or disorders that are encompassed by the instant invention. The assumption that compounds having SEQ ID Nos. 1-10 may be used to treat, image, or elicit somatostatin receptor effects all diseases embraced by the claims is an incredible finding for which Applicants have not provided supporting evidence. Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the methods as claimed.

(4) Level of predictability in the art

The art pertaining to the treatment of diseases/conditions is highly unpredictable. Determining the various types or classes of diseases/conditions treatable with the

instant invention requires various experimental procedures and without guidance that is applicable to all diseases/conditions, there would be little predictability in performing the claimed invention.

(5) Amount of direction and guidance provided by the inventor

There is no evidence of record which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the numerous diseases/conditions claimed herein. There is no directional guidance for the types or classes of diseases/conditions that are treatable. The evidence of record does not provide as to exactly what diseases/conditions Applicant is treating, imaging, or eliciting a somatostatin receptor effect. Hence, there is no enablement for all possible diseases/conditions claimed.

(6) Existence of working examples

The claims encompass a vast number of diseases/conditions. Applicant's working examples do not disclose the administering of compounds having SEQ ID Nos. 1-10 used in the claimed methods.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible diseases/conditions known to exist.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the

specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

112 First Paragraph Rejection (Inhibiting Claims)

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 17 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In particular, the instant specification does not provide enablement for the inhibiting the proliferation of Helicobacter pylori in a mammal.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7)

breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to methods of inhibiting the proliferation of Helicobacter pylori in a mammal.

(2) State of the prior art

The references of record do not indicate that the compounds of claim 1 may be used in inhibiting the proliferation of Helicobacter pylori in a mammal.

(3) Level of one of ordinary skill in the art

Applicant's specification does not disclose or enable the public to inhibit the proliferation of Helicobacter pylori in a mammal.

(4) Level of predictability in the art

The art pertaining to the inhibition of a condition, Helicobacter pylori, is highly unpredictable. Determining whether or not Helicobacter pylori is inhibited (prevented) requires various experimental procedures and without guidance to insure that the subject *never* experiences any characteristics associated with Helicobacter pylori. Hence, the amount of guidance present in the specification, the absence of data in the instant disclosure indicating that the symptoms of Helicobacter pylori do not occur when compounds of independent claims 1 and 11 are administered, one would not be able to ascertain whether or not Helicobacter pylori may be inhibited.

(5) Amount of direction and guidance provided by the inventor

There is no directional guidance for inhibiting Helicobacter pylori if a compound of claim 1 or 11 is administered.

(6) Existence of working examples

Applicant's working examples do disclose the administering of compounds of claims 1 and 11 to subject wherein Helicobacter pylori is inhibited.

(7) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention and the state of the prior art, one skilled in the art could not perform the claimed invention without undue experimentation.

112 Second Paragraph Rejection

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 9, 10, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9: The claim as amended is ambiguous because it is unclear what cell proliferative disorder(s) Applicant is referring to that are capable of being treated with the compounds of claim 1.

Claim 10: The claim contains improper Markush terminology. Specifically, Markush terminology requires 'closed' (i.e., selected from the group consisting of), not 'open' (i.e., comprises) language. Applicant is respectfully requested to review MPEP 803.02 and make the appropriate correction(s). In addition, Applicant is respectfully requested to replace 'and/or' with 'and'.

Claim 15: The claim as written is ambiguous because it is unclear what somatostatin receptor effect is being elicited.

REJOINDER OF CLAIMS

9. Claims 1-7 and 11-14 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 8-10 and 15-19, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 12/2/09 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be

subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

PRIORITY DOCUMENT

10. In the office action mailed 7/6/10, the Examiner indicated that a certified copy of the priority document to confirm Applicant's claim for foreign priority based on an application filed in Japan was not of record. In particular, a certified copy of Japan 2003-208390 filed 8/22/03 needs to be made of record as required by 35 UC 119(b).

Applicant responded to the Examiner's assertions by stating that it is unclear where Applicant's reference a Japanese application.

The Japanese document is listed on the Bibliographic Data Sheet (see attachment). Also, on the filing receipt confirmation mailed to Applicant on 11/15/06, the Japanese document is listed. The confirmation filing receipt indicated that if an error was found that Applicant was to contact the USPTO. As of the current date, there is no indication that the listing of the document is an error. Thus, Applicant is respectfully requested to review the documents and make the appropriate corrections, if needed.

ALLOWABLE CLAIMS

11. Claims 1-7 and 11-14 are allowable over the prior art of record.

COMMENTS/NOTES

12. It should be noted that no prior art has been cited against the compounds of independent claim 1. In particular, the compounds are distinguished over the prior art

because the prior art neither anticipates nor renders obvious compounds having SEQ ID Nos. 1-10.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/
Primary Examiner
Art Unit 1618

November 30, 2010